REMARKS

Claims 1-17 are pending in the instant application. Claims 6 and 9-17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5, 7 and 8 have been rejected. Claims 1, 2, 3, 4, 5 and 8 have been amended. Support for these amendments is provided in the specification at page 33, line 12. The specification has also been amended to correct inadvertent typographical errors at page 129, lines 5 through 12. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed March 3, 2003. Thus, in an earnest effort to advance the prosecution of this case, Applicants are canceling nonelected claims 6 and 9-17 without prejudice. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Amendment of Title

The Examiner suggests that the title of the invention is not descriptive of the invention to which the claims are directed. Therefore, Applicants have amended the title to state:

Colon Specific Nucleic Acids, Vectors and Host Cells

in accordance with the subject matter identified by the Examiner as being claimed.

III. Objection to Specification

The specification has been objected to as containing

embedded hyperlinks and/or other forms of browser executable code. It is respectfully pointed out, however, that Applicants have no intention of having these hyperlinks be active links. Instead, these hyperlinks and/or other forms of browser-executable codes describe enabling methodologies for use with the claimed invention and therefore have been included in the patent application in order to comply with the requirements of 35 U.S.C. § 112, first paragraph. Thus, in accordance with MPEP § 608.01(p), Applicants should not be required to remove these citations from the specification.

Withdrawal of this objection is therefore respectfully requested.

IV. Objection to Claim 1

Claim 1 has been objected to as including non-elected subject matter. Thus, in an earnest effort to advance the prosecution of this case and in accordance with the Examiner's suggestion, Applicants have amended claim 1 to delete nonelected subject matter. Withdrawal of this rejection is therefore respectfully requested.

V. Rejection of Claim 1-5, 7 and 8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 101 because the Examiner suggests that the claimed invention lacks patentable utility due to its not being supported by a specific, substantial and credible utility or, in the alternative, a well-established utility. These claims have also been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

The Examiner suggests that the instant specification lacks data and sound scientific reasoning so that it is speculative whether the polynucleotide of SEQ ID NO:5 plays a role in the asserted utilities.

Applicants respectfully traverse these rejections.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that a specific utility for SEQ ID NO:5 has not been established simply because the disclosed uses of these compositions are generally applicable to colon cancer polynucleotides.

By "specific utility" it is not meant that no other compound may share a similar utility to that of the present invention. Instead, MPEP § 2107.01 contrasts specific utility, which is specific to the subject matter claimed, from general utility, which is applicable to a broad class of the invention. As described in detail at page 2100-32 of the MPEP, a general utility is, for example, a teaching that a compound is useful for treating an unspecified disorder, or has useful, but undefined biological properties, or is useful as a gene probe wherein no DNA target is defined. In contrast, an example of a specific utility set forth at page 2100-32 of the MPEP is the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition.

The instant specification discloses a specific biological activity for polynucleotides of the present invention including SEQ ID NO:5. See specifically, Example 1 at pages 116-121

wherein CLASP™ scores are provided for SEQ ID NO:5 which are indicative of this nucleic acid sequence exhibiting statistically significant expression in the tissue of interest, namely colon tissue, and exhibiting detectable expression in colon cancer tissue and undetectable expression in normal tissue. As taught at page 116, CLASP™ is not merely a software program, as suggested by the Examiner, but rather provides a set of algorithms that interrogate a database of gene expression data to identify genes differentially expressed in selected tissues as well as cancerous tissues. Thus, SEQ ID NO:5 is taught to have the specific biological activity of being colon cancer specific by these data. Such teachings clearly establish a credible specific utility for nucleic acid sequences identified in the present invention as diagnostic markers for colon cancer.

The case law is also quite clear; mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:5 as a colon cancer gene constitutes a pharmacological activity relevant to the asserted use as a diagnostic for colon cancer, thus satisfying the utility requirement.

Further, Applicants respectfully disagree with the Examiner's unsupported allegation that basing gene expression analysis solely on a CLASP software program does not immediately identify a "real world" or substantial utility and is "unpredictable". As discussed supra, CLASP™ is much more than a "software program". As taught at page 116 of the

specification, CLASP™ provides a set of algorithms that interrogate a database of gene expression data to identify genes differentially expressed in selected tissues as well as cancerous tissues. Further, a specific or substantial utility is one wherein the utility is "credible" to one of skill in the art, not "predictable". In accordance with MPEP § 2107.02, an assertion is "credible" unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. In the instant application, the logic underlying the assertion of utility is neither flawed nor based on facts inconsistent with the logic underlying the assertion.

Thus, since the instant specification provides a specific and substantial utility for SEQ ID NO:5 supported by logic and facts consistent with this logic, the instant specification meets the utility requirements as set forth in 35 U.S.C. § 101 and the enablement requirements for use as set forth in 35 U.S.C. § 112, first paragraph.

Withdrawal of these rejections is therefore respectfully requested.

VI. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, first paragraph - Lack of Written Description

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the invention was filed, had possession of the claimed invention. The Examiner has acknowledged that the specification

meets the written description requirements for SEQ ID NO:5 and its full complement. However, the Examiner suggests that claims 1-5, 7 and 8 are directed to sequences that hybridize to SEQ ID NO:5 and sequences having a recited degree of homology of 60% which do not meet the written description provision of 35 U.S.C. § 112, first paragraph.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to delete reference to hybridizing sequences and to specify that the sequence have 99.5% homology with SEQ ID NO:5. Support for this amendment is provided in the specification at page 33, line 12.

Applicants believe that the pending claims as amended, which are clearly supported by the specification, set forth definitive structural features of the claimed polynucleotides so that one of skill in the art can predictably identify the encompassed molecules as being identical to those now claimed. Further, the claims as amended describe distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention. See MPEP § 2163.02. Thus, the claims as amended meet the written description requirements of 35 U.S.C. § 112, first paragraph.

Withdrawal of this rejection is therefore respectfully requested.

VII. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, second paragraph

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which the applicant regards as the invention.

Specifically, the Examiner suggests that recitation of the phrase "selectively hybridizes" in claim 1 is vague and indefinite because is it unclear which hybridizing criteria such as stringency conditions or low, medium or high stringency is meant.

Applicants respectfully disagree.

MPEP § 2173 requires that definiteness of claim language be assessed in light of the teachings of the specification. In the instant specification, detailed teachings for assessing selective hybridization are set forth at pages 14 through 17. Thus, what is meant by selective hybridization in the claims is clear when read in light of the teachings of the specification.

However, in an earnest effort to advance the prosecution of this case, claim 1 has been amended to delete this phrase.

The Examiner also suggests that the phrase "according to" in claims 2-5 and 8 is vague and indefinite. Applicants respectfully disagree since this phrase is used routinely by practitioners in dependent claims to refer back to the independent claim. However, in an earnest effort to advance the prosecution of this case, Applicants have replaced this phrase with the term "of".

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is therefore respectfully requested.

VIII. Rejection of Claims 1, 2, 4 and 5 under 35 U.S.C. § 102(a)

Claims 1, 2, 4 and 5 have been rejected under 35 U.S.C. § 102(a) as being anticipated by GenBank Accession Number AK025743.

The Examiner suggests that the homo sapien cDNA sequence of GenBank Accession Number AK025743 has 99.3% similarity to SEQ ID NO:5 (residues 1-2373).

Thus, in accordance with teachings at page 33, line 12 of the specification, Applicants have amended claim 1 to state 99.5% sequence identity to SEQ ID NO:5.

Since the cited reference does not teach a sequence within the claimed percent identity, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(a) is therefore respectfully requested.

IX. Rejection of Claims 1, 3, 4 and 5 under 35 U.S.C. § 102(b)

Claims 1, 3, 4 and 5 have been rejected under 35 U.S.C. § 102(b) as being anticipated by GenBank Accession Number AP000067. The Examiner suggests that residues 48624-50997 of the homo sapien genomic DNA sequence of GenBank Accession Number AP000067 has 99.2% similarity to SEQ ID NO:5 (residues 1-2375).

Thus, in accordance with teachings at page 33, line 12 of the specification, Applicants have amended claim 1 to state 99.5% sequence identity to SEQ ID NO:5.

Since the cited reference does not teach a sequence within the claimed percent identity, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

X. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 102(e)

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Endege et al. (U.S. Patent

6,262,334). The Examiner suggests that the word "hybridizes" in claim 1 encompasses fragments and Endege teaches a human gene fragment (SEQ ID NO:202, residues 332-349) which matches 100% with residues 628-645 of the instant invention and nucleic acids which hybridize to SEQ ID NO:202. The Examiner also suggests that Endege et al. teaches vectors using SEQ ID NO:202 which can be used to express a gene in a host cells.

It is respectfully pointed out, however, that the claims, as amended, are not drawn to hybridizing sequences. Accordingly, the Examiner's basis for this rejection is now moot.

Withdrawal of this rejection under 35 U.S.C. § 102(e) is therefore respectfully requested.

XI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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